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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,512	05/23/2006	Yoshitaka Ichikawa	8031-013-US	2374

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EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,512	ICHIKAWA ET AL.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-92* is/are pending in the application.

4a) Of the above claim(s) *3-6,12-21 and 47-92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-11 and 22-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/23/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group XVII, Claims 1, 2, 7-11 and 22-46 in the reply filed on July 6, 2009 is acknowledged. The traversal is on the grounds that the claims as presently restricted would not create a serious burden to search and examine since the present restriction covers overlapping subject matter, namely methods drawn to treating various joint conditions using animosugar derivatives, especially groups XVII to XX as pointed out by Applicants, which are all drawn to cartilage degradation. This argument is not found persuasive because the various groups are drawn to a method of treating specific arthritis conditions using different compounds. All-though, groups XVII to XX, for example, are all drawn to treating cartilage degradation, it would be a burden to search and examine each of the groups of claims since the each group is drawn to treating the degradation with a different compound. A reference used to reject claims drawn to the method of treating cartilage degradation with derivatives of glucosamine, would not cover a rejection of the claims that treats cartilage degradation with derivatives of cyclitol.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3-6, 12-21 and 47-92 are withdrawn from consideration as being directed to non-elected inventions.

Information Disclosure Statement

3. The information disclosure statement filed July 23, 2007 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. See the Bohne, W. Med. Welt. Nr. reference.

4. The information disclosure statement filed July 23, 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. See the Dieppe, P. and the Setnikar, I. et al references. These references are not legible. A copy of the Fingl, E. et al was not provided.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 43-46 the phrase "said condition" lacks clear antecedent basis which renders the claims indefinite since Claim 1, from which Claims 43-46 are dependent from, does not recite a condition, per se.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 7-11, 22-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Lotz et al (WO 02/078445 A1).

Applicants claim a method of treating an osteoarthritis related disorder in a mammal comprising administering a compound to said mammal, wherein said compound further comprises a therapeutically effective amount of an aminosugar

derivative, wherein said aminosugar derivative is selected from the group consisting of a derivative of glucosamine, a derivative galactosamine, a derivative of cyclitol, a derivative of iminocyciitol, and pharmaceutically acceptable salts thereof.

The Lotz et al publication discloses a method of treating cartilage degradation in a patient that involve administering to a patient a composition containing a therapeutically effective amount of N-acetylglucosamine which exhibits antiinflammatory and chondroprotective properties by interfering with cytokine-inducible gene expression in chondrocytes, wherein the N-acetylglucosamine may be used alone or in combination with at least one other anti-inflammatory drug or a hexoaminidase inhibitor. The Lotz et al publication discloses administration of the N-acetylglucosamine using intra-articular, topical and intramuscular methods (see page 4, 1st and 3rd paragraphs, page 10, 4th and 5th paragraphs, page 12, last paragraph and page 17, 3rd paragraph). The structure of Formula V recited in instant Claims 9 and 11 anticipates N-acetyl glucosamine when X is O, R_1 is hydroxyl, R_2 is acetyl and when R_3 is hydroxyl. The above description of the method of treating cartilage degradation in the Lotz et al publication anticipates the instantly claimed method of treating osteoarthritis related disorder in a mammal when the related disorder is cartilage degradation. The protein binding capability of the derivative of glucosamine in instant Claims 26-28 is an inherent property of N-acetylglucosamine in view of the structure of the N-acetylglucosamine.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 2, 7-11 and 22-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lotz et al (WO 02/078445 A1) in view of Menard et al (US Patent No. 6,838,451).

Applicants claim a method of treating an osteoarthritis related disorder in a mammal comprising administering a compound to said mammal, wherein said compound further comprises a therapeutically effective amount of an aminosugar derivative, wherein said aminosugar derivative is selected from the group consisting of a derivative of glucosamine, a derivative galactosamine, a derivative of cyclitol, a derivative of iminocyciitol, and pharmaceutically acceptable salts thereof.

The Lotz et al publication discloses a method of treating cartilage degradation in a patient that involve administering to a patient a composition containing a therapeutic-cally effective amount of N-acetylglucosamine which exhibits antiinflammatory and chondroprotective properties by interfering with cytokine-inducible gene expression in chondrocytes, wherein the N-acetylglucosamine may be used alone or in combination with at least one other anti-inflammatory drug or a hexoaminidase inhibitor. The Lotz et al publication discloses administration of the N-acetylglucosamine using intra-articular, topical and intramuscular methods (see page 4, 1st and 3rd paragraphs, page 10, 4th and 5th paragraphs, page 12, last paragraph and page 17, 3rd paragraph). The above

description of the method of treating cartilage degradation in the Lotz et al publication embraces the instantly claimed method of treating osteoarthritis related disorder in a mammal when the related disorder is cartilage degradation.

The instantly claimed method of treating cartilage degradation differs from the cartilage degradation treatment disclosed in the Lotz et al publication by claiming that the method consists of preventing cartilage degradation.

The Menard et al patent discloses a method of administering a composition to prevent cartilage degradation (see column 3, 3rd paragraph) wherein a component of the composition is glucosamine (column 1, lines 59 and 60).

One of ordinary skill in this art would be motivated to combine the teaching of the Lotz et al publication with the teaching of the Menard et al patent to reject the instant claims since both references disclosed methods of treating cartilage degradation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the method of administering N-acetylglucosamine to treat cartilage degradation of the Lotz et al publication a method wherein the treatment includes preventing cartilage degradation in view of the recognition in the art, as evidenced by Menard et al patent, that glucosamine compounds are known component of compositions that have been used as therapeutic agents for preventing cartilage degradation.

Summary

11. Claims 1, 2, 7-11 and 22-46 are rejected; Claims 3-6, 12-21 and 47-92 are withdrawn from consideration.

Examiner's Telephone Number, Fax Number, and Other Information

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623